DOCKET NO.: DOVP-1-0901 PATENT

Current Status of the Claims:

This listing of claims will replace the listing of claims in the application:

Listing of Claims:

- 1. (Cancelled).
- 2-4. (Withdrawn).
- 5. (Cancelled).
- 6-8. (Withdrawn).
- 9. (Cancelled).
- 10. (Previously Presented) The unit oral dosage form of claim 16 wherein said composition is in the form of a tablet.
- 11. (Previously Presented) The unit dosage form of claim 16 wherein the hydroxypropyl methyl cellulose polymer matrix is present in an amount of from about 20% to 40% by weight of this composition.
- 12. (Previously Presented) The unit dosage form of claim 16 wherein said polymer matrix has a viscosity of from about 100 to about 100,000 cps.
- 13. (Previously Presented) The unit dosage form of claim 10 wherein said active ingredient is present in an amount of 200 mg to 400 mg.
- 14-15. (Withdrawn).
- 16. (Previously Presented) A unit oral dosage form comprising a composition containing from about 25 to 600 mg of an active ingredient selected from the group consisting of a compound of the formula

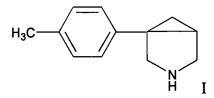
and a pharmaceutically acceptable salt thereof,

from about 15% to about 50% of weight of said composition of a hydroxypropyl methyl cellulose hydrophilic slow release polymer matrix.

- 17. (Previously Presented) The unit dosage form of claim 16 wherein said dosage form contains a pharmaceutically carrier composition containing calcium phosphate.
- 18. (Previously Presented) The unit dosage form of claim 17 wherein said carrier is present in an amount of from about 40% to 60% by weight of said composition.

19-25. (Withdrawn)

26. (Previously Presented) A pharmaceutical composition comprising:
a pre-determined dosage amount of an active ingredient selected from a
compound of Formula I



and pharmaceutically acceptable salts thereof; and

a sustained release vehicle.

- 27. (Previously Presented) The composition of claim 26, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.
- 28. (Previously Presented) The composition of claim 26, wherein said predetermined dosage amount of the active ingredient is about 100 mg, about 200 mg, about 400 mg, or about 600 mg.
- 29. (Previously Presented) The composition of claim 26, wherein said pharmaceutically acceptable salts are selected from the group consisting of

hydrochloride, phosphate, citrate, fumarate, maleate, succinate, pamoate, and sulfate acid-addition salts.

- 30. (Previously Presented) The composition of claim 26, wherein said compound of formula I is formulated with a sustained release vehicle in an oral dosage composition which, following administration of the composition to a mammalian subject provides not less than 10% of the compound of formula I released within 15 minutes and not less than 50% of the compound of formula I released within 4 hours and not less than 85% by weight of the compound of formula I released within 12 hours.
- 31. (Previously Presented) The composition of claim 26, wherein said sustained release vehicle is a sustained release polymer.
- 32. (Previously Presented) The composition of claim 26, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 33. (Previously Presented) A pharmaceutical composition comprising: a pre-determined dosage amount of an active ingredient selected from a compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, said composition formulated in an oral dosage form having a sustained release dissolution profile using USP1 apparatus, 20 mesh baskets, 75 rpm, 900 ml phosphate buffer pH 6.8 ± 0.05 , 37° C $\pm 0.05^{\circ}$ C wherein between about 9.2%-17.7% of said compound is released within approximately 0.25 hours.

- 34. (Previously Presented) The composition of claim 33, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.
- 35. (Previously Presented) The composition of claim 33, wherein said sustained release vehicle is a sustained release polymer.
- 36. (Previously Presented) The composition of claim 35, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.

37. (Previously Presented) A pharmaceutical composition comprising: a pre-determined dosage amount of an active ingredient selected from a compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, said composition formulated in an oral dosage form having a sustained release dissolution profile using USP1 apparatus, 20 mesh baskets, 75 rpm, 900 ml phosphate buffer pH 6.8 ± 0.05 , 37° C $\pm 0.05^{\circ}$ C wherein between about 42.9%-57.4% of said compound is released within approximately 4.0 hours.

- 38. (Previously Presented) The composition of claim 37, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.
- 39. (Previously Presented) The composition of claim 37, wherein said sustained release vehicle is a sustained release polymer.
- 40. (Previously Presented) The composition of claim 39, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 41. (Previously Presented) A pharmaceutical composition comprising:
 a pre-determined dosage amount of an active ingredient selected from a
 compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, said composition formulated in an oral dosage form having a sustained release dissolution profile using USP1 apparatus, 20 mesh baskets, 75 rpm, 900 ml phosphate buffer pH 6.8 ± 0.05 , 37° C $\pm 0.05^{\circ}$ C wherein between about 65.7%-99.9% of said compound is released within approximately 12.0 hours.

42. (Previously Presented) The composition of claim 41, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.

43. (Previously Presented) The composition of claim 41, wherein said sustained release vehicle is a sustained release polymer.

44. (Previously Presented) The composition of claim 43, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.

45. (Previously Presented) A pharmaceutical composition comprising:
a pre-determined dosage amount of an active ingredient selected from a
compound of Formula I

$$H_3C$$

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, which following administration of the composition to a mammalian subject provides a maximum plasma concentration (Cmax) of said compound in the subject that is less than about 37% of a Cmax provided in a control subject after administration of the same amount of said compound in a rapid release formulation.

- 46. (Previously Presented) The composition of claim 45, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.
- 47. (Previously Presented) The composition of claim 45, wherein said sustained release vehicle is a sustained release polymer.
- 48. (Previously Presented) The composition of claim 43, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 49. (Previously Presented) The composition of claim 45, which following administration of the composition to a mammalian subject provides a maximum plasma concentration (Cmax) of said compound in the subject that is between about 27%-37% of a Cmax provided in a control subject after administration of the same amount of said compound in a rapid release formulation.